ZIMMER BIOMET

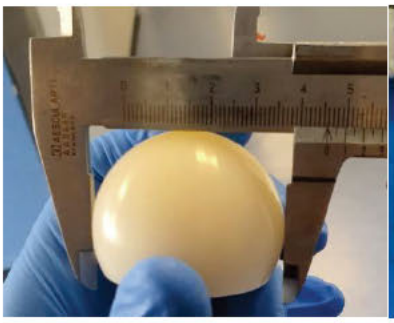
13 October 2025

To: Hospitals and Surgeons

Subject: **URGENT MEDICAL DEVICE FIELD SAFETY CORRECTIVE ACTION (REMOVAL)**

Affected Product: Dual Mobility Vivacit-E® Vitamin E Bearing

Material Number	Material Description	Batch Number	UDI Number
110031012	Dual Mobility Vivacit-E® Vitamin E Bearing, 44 mm O.D, Size F	67160447	(01)00889024572706(17)300406(10)67160447
110031013	Dual Mobility Vivacit-E® Vitamin E Bearing, 46 mm O.D, Size G	67160480	(01)00889024572713(17)300406(10)67160480



Zimmer Inc. is conducting a medical device Field Safety Corrective Action for two batches of the Dual Mobility Vivacit-E Bearing due to a commingle. The outer package is labeled as a Size F 44 mm, however, the implant inside the package is a Size G 46 mm, and vice versa. Two product complaints have been received that identified the size discrepancy at the point of use during the procedure.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	No patient, user, or other stakeholder harm occurs, and the procedure is completed with a different device.	Immediate revision of the implant construct to correct the issue.
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	Joint kinematics are adversely impacted (such as dislocation or disassociation of components) necessitating surgical intervention.	Osteolysis or bearing failure necessitates surgical intervention.

Our records indicate that you may have received one or more of the affected products. The affected products were distributed between August and September 2025.

ZIMMER BIOMET

Hospital Responsibilities

1. Review this Field Safety Notice and ensure that affected personnel are aware of the contents.
2. Immediately locate and quarantine any affected product in your inventory. Your Zimmer Biomet sales representative may assist with removing the affected product(s) from your facility.
3. If any affected product has been further distributed, provide your customer(s) with this Field Safety Notice and ensure documentation.
4. Complete **Attachment 1 – Certificate of Acknowledgement** and send it to fieldaction.netherlands@zimmerbiomet.com. This form must be returned even if you do not have any affected product available for return.
5. Retain a copy of **Attachment 1 - Certificate of Acknowledgement** with your records in the event of a compliance audit of your facility.
6. If you have further questions or concerns after reviewing this Field Safety Notice, please contact your local Zimmer Biomet representative.

Surgeon Responsibilities:

1. Review this Field Safety Notice for awareness of the contents.
2. If the product has been implanted, Zimmer Biomet recommends assessing the patient with imaging and monitoring the patient for the potential health risks.
   a. In addition to the recommended patient monitoring instructions, this Field Safety Notice provides a plain language description in **Appendix A – Post-Operative Patient Information** that you may provide to your impacted patients at your discretion.
3. If you have further questions or concerns after reviewing this Field Safety Notice, please contact your local Zimmer Biomet representative.

Other Information

This Field Safety Corrective Action was reported to all relevant Competent Authorities and Notified Bodies as required under the applicable regulations for Medical Devices per Regulation (EU) 2017/745 and guidance MDCG 2023-3. The undersigned confirms that this Field Safety Notice has been delivered to the appropriate Regulatory Agencies. Please be aware that the names of user facilities notified are routinely provided to the Competent Authorities for audit purposes.

Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing per.nl@zimmerbiomet.com.

We would like to thank you for your co-operation in advance and regret any inconvenience caused by this Field Safety Corrective Action.

Sincerely,

ZIMMER BIOMET

ATTACHMENT 1 - Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Field Safety Corrective Action reference number: ZFA-2025-00219
Affected Product: Dual Mobility Vivacit-E® Vitamin E Bearing

Do you have affected product(s) in your facility?
☐ Yes, we currently have one or more affected products in our facility.
☐ No, we currently have no affected items in our facility.
Note: *Any product not available for return is considered dispositioned under your distributorship and unavailable for use.*

Complete the table below for all affected products returned. If additional space is needed, please provide a spreadsheet and return it with this form. **Do not return products with other returns.**

Material Number	Batch Number	Quantity Returned
110031012	67160447	
110031013	67160480	

Hospital acknowledgement

By signing below, I acknowledge that I have received, read, and understand the contents of this Field Safety Notice. All required activities are complete or are being completed.

Facility Name					
Facility Address					
Post Code		**City**		**Country**	
Printed Name					
Title					
Date		**Signature**			

ZIMMER BIOMET

APPENDIX A - Post-Operative Patient Information

To: Patients

Subject: **Post-Operative Patient Information Regarding the Dual Mobility Vivacit-E® Vitamin E Bearing**

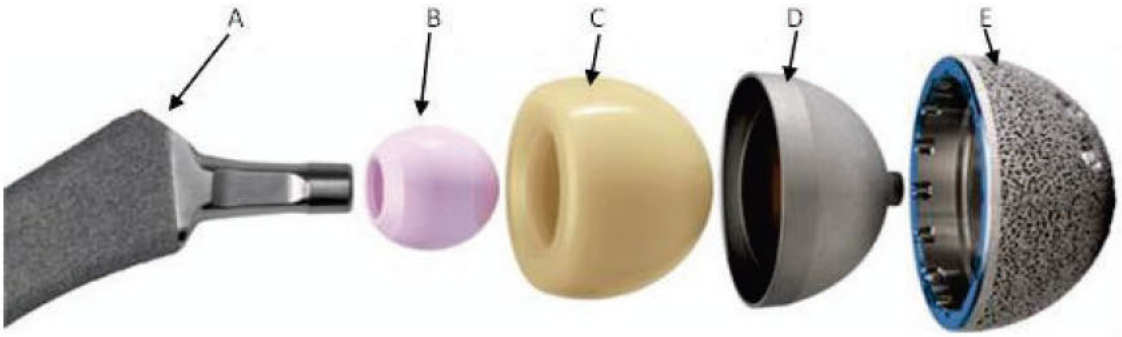
Affected Product: Dual Mobility Vivacit-E® Vitamin E Bearing

Material Number	Material Description	Batch Number
110031012	Dual Mobility Vivacit-E® Vitamin E Bearing, 44 mm O.D, Size F	67160447
110031013	Dual Mobility Vivacit-E® Vitamin E Bearing, 46 mm O.D, Size G	67160480

This information is for patients who received a hip replacement with the products in scope of the Field Safety Corrective Action with reference number ZFA-2025-00219 that were manufactured by Zimmer Inc. The affected products are listed in the table above.

More specifically, Zimmer Inc. is conducting a voluntary medical device Field Safety Corrective Action (removal) related to the Dual Mobility Vivacit-E® Vitamin E Bearing due to an issue where the product inside the box was the incorrect size compared to the product labeling. The product inside the box may have been 2 mm larger or 2 mm smaller than the product label description.

The dual mobility hip replacement procedure consists of five components:
A. The femoral stem that inserts into the femoral bone.
B. The femoral head that inserts into the polyethylene (plastic) bearing.
C. The polyethylene (plastic) bearing that connects with the head and is the bearing between the head and liner. ***This is the affected component.***
D. The metal liner that connects with the plastic bearing and acetabular shell.
E. The metal acetabular shell that is attached to the hip socket.



All hip replacement products have potential risks associated with their use, including potential impact to joint movement after surgery. If you have been experiencing any pain, difficulty when walking, inability to bear weight, swelling, instability of the hip or range-of-motion limitations, it is recommended that you follow-up with your surgeon or another health care provider for further evaluation.

Although you should be aware of the potentially increased risk of potential impact to joint movement after surgery, an increased risk does not necessarily mean that the potential health risks will occur or that revision surgery is required to remove the recalled device. You should consult with your surgeon for further evaluation, as necessary.

Removal of any hip arthroplasty when a patient is not experiencing any symptoms is not recommended and patients should continue normal follow-up with their surgeon or health care provider unless they are experiencing unexpected symptoms. You may refer to your health care provider or surgery center to obtain your operation implant information records to identify the used material and batch number(s).

Questions regarding the Dual Mobility Vivacit-E® Vitamin E Bearing or any other Zimmer Biomet hip product should be directed to your health care provider, surgery center or fieldaction.netherlands@zimmerbiomet.com.

Complaints related to the Dual Mobility Vivacit-E® Vitamin E Bearing or any other Zimmer Biomet hip product should be reported to your health care provider or surgery center and can be reported to per.nl@zimmerbiomet.com for investigation, potential regulatory reporting and monitoring.

Patient health and safety are top priorities at Zimmer Biomet. We appreciate your time and attention in reading this important information.

Sincerely,